

REMARKS/ARGUMENTS

Applicant has elected to continue prosecution of Group I claims in response to the Examiner's restriction requirement. Non-elected claims from Group II, consisting of claims 4, 8, 15, 19, 24, 30, and 33 have been withdrawn from consideration by the Examiner as drawn to a non-elected invention. Applicant therefore cancels claims 4, 8, 15, 19, 24, 30 and 33 without prejudice. Applicant agrees that claims 1, 6, 12, 17, 21, 27 and 31 are generic.

The objected-to informality in claim 13 has been obviated by amendment in accordance with the Examiner's suggestion. Claims 28, 29, 30, 32, and 33 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claims 30 and 33 have been cancelled without prejudice. Claims 28, 29 and 32 have been corrected by amendment to depend from the correct independent claims.

Claims 1, 2, 3, 5, 6, 7, 9, 27, 28, 29, 31, and 32 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the Farascioni *et al.* reference. Applicant respectfully traverses the Examiner's position that Farascioni anticipates the claimed subject matter. Fig. 8 of the Farascioni reference does not disclose radiopaque markings on penetration tip 92 (Fig. 8, col. 9, line 6 – col. 10, line 8). Farascioni discloses at col. 15, lines 20-23 that an “[o]uter tube 458 is preferably provided with radiopaque lines formed to indicate the longitudinal spacing of tissue basket 434 in order to provide the user with an indication of the tissue sampling area.” However, Farascioni does not disclose providing radiopaque indicia directly on a cutting member as claimed in the present application. The outer tube 458 described in Farascioni merely contains a stainless steel knife tube 414 that does not have radiopaque indicia. A reference cited as prior art under 35 U.S.C. § 102(e) must disclose every element of an anticipated invention. Regarding claim 1, Applicant respectfully asserts that the citation of the Farascioni *et al.* reference is not a proper basis for rejection of this claim under 35 U.S.C. § 102(e).

Regarding claims 2, 3, 6, 7, 27, 28, 29, 31, and 32, the Examiner states that lines shown in Fig. 8 of the Farascioni reference act as reference points to determine the length of the deployed cutting member. Applicant respectfully traverses the Examiner's view of the Fig. 8

disclosure. Fig. 8 does not disclose lines acting as reference points, either pictorially or within the description accompanying the illustration at col. 9, line 60 to col. 10, line 3. Furthermore, claims 2, 3, 6, 7, 27, 28, 29, 31 and 32 include limitations to radiopaque reference point and/or radiopaque indicia and not to “lines.” The Examiner has not cited to Fig. 8 of the reference as containing radiopaque reference points as claimed in the current subject matter.

Claims 5 and 9 include the limitation “radiopaque indicia are referenced from a middle of said cutting member and alternate along a length of said cutting member.” This phrase is part of a structural recitation describing the location of radiopaque indicia on the claimed cutting member, and one of ordinary skill in the art would recognize that this element is structural in nature and not part of a method recitation. Claim 5 and 9 are not anticipated by the cited reference, as Farascioni does not disclose the use of radiopaque indicia on a cutting member referenced from the middle of the cutting member.

Claims 10, 11, 21, 22, 23, 25, and 34 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Werner. Applicant traverses the Examiner’s rejection of these claims as the Werner reference does not anticipate the claimed subject matter. Werner describes a retractable scalpel and does not describe an endoscopic catheter, nor a needle knife. Werner does not describe a cable actuated needle knife. The perspective view of the scalpel shown in Fig. 2 of shows a spring, not a cable actuated needle knife.

Regarding claims 21, 22, 23, and 34, the Examiner states that Werner discloses detents (50) on a cutting member, which act as a visual indicator as to the extension of a surgical blade. Applicant respectfully traverses the Examiner’s statement regarding the Werner disclosure. The Werner reference discloses “[a] plurality of holes (50) [that] are disposed on a top side and a bottom side (not shown) of the sheath member (42).” Col. 7, lines 7-8. Werner does not disclose visual indicia placed directly on the cutting member. Claims 21, 22, 23, and 34 claim the improvement comprising providing a *cutting member* (emphasis added) with a plurality of visual indicia located at visually measurable intervals.

Regarding claim 25, it is the Applicant's position that the Examiner has misconstrued this claim in the same manner as claims 5 and 9, as discussed above. Claim 25 contains the phrase "visual indicia referenced from a middle of said cutting member," which is a structural limitation and not a method recitation. The Werner reference does not disclose placing visual indicia on a cutting member, and does not disclose visual indicia referenced from a middle of a cutting member. The Werner reference does not contain every element of the claimed subject matter, and therefore does not anticipate Claims 10, 11, 21, 22, 23, 25, and 34 under 35 U.S.C. § 102(b).

Claims 12, 13, 14, 16, 17, 18, and 20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Werner in view of Farascioni. To establish *prima facie* obviousness for a claimed invention, all claim limitations must be taught or suggested by the prior art. *In re Roy*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.P.A. 1974). The Examiner contends that Werner discloses a surgical endoscopic catheter containing a needle knife on the end and that the Farascioni reference teaches an endoscopic needle knife with radiopaque markings along the length of the cutting member. Applicant respectfully traverses the Examiner's contentions. Werner discloses a "surgical blade (46), which is mounted on a front end (48) of the blade support assembly (44), [that] is shielded in the sheath member (42)." Col. 7, lines 4-7. Applicant does not view Werner as disclosing a surgical endoscopic catheter. Farascioni teaches a surgical biopsy apparatus with a radiolucent outer tube "preferably provided with radiopaque lines" that is separate from a "radiopaque stainless steel knife tube 414", col 15, lines 19-21. Farascioni does not teach providing a cutting member itself with radiopaque indicia. The Examiner also states that the inclusion of radiopaque markings as taught by Farascioni in view of the Warner disclosure would render obvious a claim directed to providing "the user with an indication of the tissue sampling area." Claims 12, 13, 14, 16, 17, 18, and 20 do not contain the above element as a limitation. Because neither Werner nor Farascioni disclose or suggest providing a cutting member with radiopaque indicia, and because neither reference provides motivation for providing a cutting member with radiopaque indicia, the claimed subject matter is not obvious over these references.

Regarding claims 13, 14, 17, and 18, the Examiner suggests that "the lines, shown in Figure 9, act as reference points to determine the length of the deployed cutting member."

However, Figure 9 and the accompanying description of Figure 9 in the Farascioni reference do not indicate that any of the lines shown may be used as reference points. Applicant respectfully traverses the Examiner's suggestion and believes that the claimed subject matter is not obvious over Farascioni in view of Warner.

Regarding claims 16 and 20, the limitation of "radiopaque indicia referenced from a middle of said cutting member" is a structural limitation and not a method recitation as construed by the Examiner, and as discussed earlier in claims 5, 9, and 25. Applicant respectfully asserts that this limitation should be given patentable weight in all claims containing the limitation. The Werner disclosure does not teach radiopaque indicia referenced from a middle of a cutting member, and the claimed subject matter is not obvious over the reference.

Claim 26 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Farascioni in view of Dretler *et al.* WO 01/01869 A1. The Examiner states that Farascioni discloses all of claim 21, but does not disclose that the visual indicia should include different color markings. Applicant respectfully traverses the Examiner's statement regarding the Farascioni reference. Farascioni does not teach providing a cutting member with a plurality of visual indicia. The Farascioni cutting member does not contain visual indicia. Therefore, the indication system taught by Dretler would not render the claimed subject matter obvious when combined with the Farascioni reference. Applicant also believes that it would not be obvious to one of ordinary skill in the art to modify the Farascioni reference to include colored visual indicia, as neither reference contains motivation to combine their teachings. Applicant respectfully requests that the Examiner withdraw his rejection of claims 12, 13, 14, 16, 17, 18, 20, and 26 based on 35 U.S.C. § 103(a)

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Applicant believes that all claims are now in condition for examination and allowance. Should the Examiner have any questions or comments regarding this communication, he may contact the Applicant's representative at the number below.

Respectfully submitted,

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